



April 19, 2017

The Honorable Tom Price, M.D.  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
Via: Thomas.Price@hhs.gov

The Honorable Jim Mattis  
Secretary  
Department of Defense  
1400 Defense Pentagon  
Washington, D.C. 20301-1400  
Via: whs.pentagon.esd.mbx.cmd-correspondence@mail.mil

Dear Secretaries Price and Mattis:

Knowledge Ecology International (KEI) is a non-profit organization with offices in Washington, DC. The Union for Affordable Cancer Treatment (UACT) is a non-profit cancer patient group. More about each group is available on their respective web pages: <http://keionline.org> and <http://cancerunion.org>.

This letter is to request that the United States Government reconsider the decision of the Obama Administration to deny our petition, initially filed in January 2016, that the government use its rights in patents under the Bayh Dole Act (35 U.S.C. §§ 200 *et seq.*) for the excessively-priced, blockbuster drug enzalutamide (marketed by Astellas Pharma as Xtandi). The initial petition highlighted the possibility of using either march-in rights under 35 U.S.C. § 203, or the royalty-free rights in the patents under 35 U.S.C. § 202(c)(4), in order to allow for generic competition and more affordable prices. The petition is attached.

The failure to act on behalf of the American people in this case was a deliberate choice made by the previous administration, to accept an outcome that has U.S. residents paying far more than any other country for a drug invented with taxpayer funding.

Given the Trump Administration's promise to make great deals for American citizens, we believe that this case is well-suited to review with new attention. In short, does the Trump

administration support a policy that Americans will pay more than patients in any other country on the planet for a medicine that was created with American tax dollars?

In the initial petition, HHS was urged to act to permit competition in the supply of the drug when the prices in the United States were higher than the median prices of countries with comparable incomes and large economies.

Moreover, in addition to the policy that the U.S. should not pay higher prices than other high income countries, the HHS should also have a policy to address the cases where high prices outside of the United States present access barriers, for example, in developing countries where prices are excessive and incomes are low.

### The KEI/UACT Xtandi Petition

The 26-page KEI/UACT petition focused on the fact that Astellas Pharma, a Japanese corporation, is currently charging American citizens more than \$130,000 per patient per year for Xtandi, an effective and important medicine for prostate cancer. That price is more than any other country in the world, and three to four times the price charged in other high-income industrialized countries, including Japan. The excessive price is in spite of the fact that the drug was developed using U.S. taxpayer money via grants from the National Institutes of Health (NIH) and the Department of Defense.

We also noted that the cost of Xtandi to Medicare has ballooned in recent years, up from \$34.9 million in 2012 to over \$447 million in 2014. In 2015, Medicare paid a total of over \$790 million for Xtandi, representing 69% of U.S. sales and 41% of global sales for the drug. Sales of Xtandi are projected to increase substantially in the coming years.

Finally, we argued that those high prices have resulted in high copayments and limited access for patients in the United States, including those who receive prescription drug benefits through Medicare.<sup>1</sup>

The KEI/UACT petition drew a significant amount of attention and support, including: a bicameral letter of support from six members of the House of Representatives and six members of the Senate; a letter of support from over fifty international non-governmental organizations; and many articles in a wide variety of media publications.<sup>2</sup>

In June 2016, Director Collins rejected the KEI/UACT petition in a two-page letter, failing to address the argument regarding high prices, and instead grounding the rejection on the absence of evidence of shortage of supply. He stated that the petition “provides no information

---

<sup>1</sup> See: <http://keionline.org/node/2485>.

<sup>2</sup> For a comprehensive set of materials and documents relating to the KEI/UACT petition, see <http://keionline.org/xtandi>.

and no information was provided from public sources to suggest that enzalutamide is currently or will be in short supply.”

KEI/UACT never argued that shortage of supply was the issue; the issue was then and remains now that a Japanese corporation is charging Americans an excessive amount, far more than anywhere else in the world, to the detriment of American patients and taxpayers. The rejection thus failed to contend with a central point of the petition — that the excessive, discriminatory prices of Xtandi are unreasonable. Director Collins also neglected to explain why the federal government should not use the royalty-free rights in the patents to address the pricing abuses. The royalty free rights are a separate provision under the Bayh Dole Act that the government may use at any time, for any reason, and without precondition, on federally-funded inventions.

KEI filed comments with the Department of the Army in a separate proceeding that are germane to this issue, and are attached here for consideration with the Xtandi petition.<sup>3</sup> In those comments, KEI addressed the statutory phrase “practical application,” defined under 35 U.S.C. § 201(f) to include “available to the public on reasonable terms,” including a discussion of the contradictory statements made by Senators Birch and Dole during their post-Senate careers on the relationship between the term “available to the public on reasonable terms” and the price the public pays. This attached submission also provided examples where the term “reasonable terms” was interpreted to include price.

### Revisiting the Petition under the Trump Administration

President Trump has rightfully spoken many times about the problem of outrageous drug prices, both during his campaign and after. In January 2017, President Trump stated that the pharmaceutical industry was “getting away with murder,”<sup>4</sup> and in his address to Congress again focused on the problem of high drug prices and his intent to “bring them down immediately.”<sup>5</sup>

President Trump’s statements echo the sentiments of a broad bipartisan consensus across the country. In a widely reported public opinion poll from October 2016, 74 percent of the American public viewed making high-cost drugs for chronic conditions affordable as a top priority for the incoming administration and Congress, and a majority of the public likewise said that government action to lower prescription drug prices was a top priority.<sup>6</sup>

---

<sup>3</sup> KEI’s comments can also be viewed here:

[http://keionline.org/sites/default/files/KEI-March\\_10\\_2017-3rd-Comments-Zika.pdf](http://keionline.org/sites/default/files/KEI-March_10_2017-3rd-Comments-Zika.pdf).

<sup>4</sup> <http://www.reuters.com/article/us-usa-trump-drugpricing-idUSKBN14V24J>

<sup>5</sup>

<http://thehill.com/policy/healthcare/321706-trump-to-congress-we-must-bring-down-drug-prices-immediately>

<sup>6</sup> <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2016/>

President Trump could take decisive action to address the problem of high drug prices in this instance by instructing the government to use its authority in this case under the existing Bayh Dole law.

#### Review of the Xtandi Petition Should Be Undertaken By An Impartial Office

If the government does proceed in reevaluating the Xtandi request, we ask that the Administration place this decision in the hands of a neutral party who does not have an established and documented predisposition against the use of government rights under Bayh Dole. It is clear from numerous statements by NIH officials, including Dr. Mark Rohrbaugh, a Special Advisor for Technology Transfer and the former head of the NIH's Office of Technology Transfer, and Director Francis Collins, that the decision on this issue should not rest with them. In December 2016, Mr. Rohrbaugh stated on several occasions that "it is not our mission to control drug prices,"<sup>7</sup> and that, "N.I.H. has made it clear that its job is not to decide prices of drugs, period."<sup>8</sup>

Similarly, Director Collins responded to questions by Senator Durbin at a hearing of the Senate Labor-HHS appropriations subcommittee on April 7, 2016 by stating that he did not believe that march-in rights under the Bayh Dole Act were intended to address problems of price but rather to address problems of access, and that he was concerned "about the negatives that may flow forward, if we use march-in rights in a very broad way about drug pricing."<sup>9</sup> To this, Senator Durbin responded that problems of access go beyond physical accessibility, saying, "if a drug is overpriced, it is not accessible."

#### Conclusion

KEI and UACT believe, along with many others, that this case continues to have merit and tremendous significance in the urgent fight against out-of-control drug prices. We believe that the Obama Administration made a mistake in not acting. And, we believe that the Trump Administration has an opportunity to rectify that mistake, and to take bold action here for the benefit of patients, consumers, and taxpayers.

We request a meeting to discuss this matter in further detail.

Sincerely,

---

<sup>7</sup> <https://www.buzzfeed.com/danvergano/nih-drug-giveaway>

<sup>8</sup>

[https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?\\_r=0](https://www.nytimes.com/2016/12/19/health/harnessing-the-us-taxpayer-to-fight-cancer-and-make-profits.html?_r=0)

<sup>9</sup> Video of this exchange is available here: <https://www.youtube.com/watch?v=wpo5sOQV9HY>



Andrew S. Goldman  
Counsel, Policy & Legal Affairs  
Knowledge Ecology International  
202-332-2670  
andrew.goldman@keionline.org

Cc: Francis Collins, M.D., Ph.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892  
Via: Francis.Collins@nih.hhs.gov